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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,674	02/15/2001	Karen W. Shannon	10971464-3	3167

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/784,674

Applicant(s)

SHANNON ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25, 27-40 and 98-147 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 9, 15-18, 20, 21, 28, 29, 98-101, 106-108 and 126-128 is/are rejected.
- 7) ☒ Claim(s) 2-4, 6, 8, 10-14, 19, 22-25, 27-40, 102-105, 109-125 and 129-147 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### *APPLICANTS' ARGUMENTS*

Applicants' arguments, filed 22 April 2005, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-25, 27-40 and 98-147. Claims 26 and 41-97 have been canceled.

### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### *NEW MATTER*

Claims 28 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 28 and all claims dependent therefrom are rejected under 35 U.S.C. § 112 1<sup>st</sup> Paragraph. Claim 28 has been amended to recite the limitation "wherein step (b) comprises

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determining at least two parameters wherein the absolute value of a correlation coefficient between said parameters is less than about 0.5.” Applicants have indicated on page 15 (lines 10-12) of the ‘*RESPONSE*’, filed 22 April 2005, that support for the amendment to claim 28 can be found in the specification on page 50, lines 46-47, which states:

“...another. In practice, the absolute value of the correlation coefficient between any two parameters should be less than 0.5, more preferably, less than 0.25, and...”

However, there is no apparent support for the broadly encompassing language “less than about 0.5” as recited in the instant claims. For instance, the specification appears to only support that the absolute value of the correlation coefficient is to be less than 0.5 and does not appear to support that such value can be greater than 0.5 as encompassed by the term “about” (additionally refer to the below 35 U.S.C. § 112 2<sup>nd</sup> Paragraph Rejection ‘*VAGUE AND INDEFINITE*’). Therefore, this is considered NEW MATTER.

#### **Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 29, 106-108, and 126-128 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

#### ***VAGUE AND INDEFINITE***

Claims 28 and all claims dependent therefrom recite the limitation “said parameters is less than about 0.5” which is considered vague and indefinite. The term “about” implies a range of values or criteria(s) defining a range considered to be “about 0.5”, which is unclear. Clarification of the metes and bounds, via clearer claim wording, is requested.

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Claims 106, 126, and all claims dependent therefrom recite the language “which selecting a subset of said clustered oligonucleotides of step (d)” which is confusing. The above language does not appear to be grammatically correct and does not provide a clear understanding of what limitations are encompassed. Clarification of the metes and bounds, via clearer claim wording, is requested.

### **Claims Rejected Under 35 U.S.C. § 102**

The rejection of claims 1, 5, 7, 9, 15, 17, 18, 20, 21, 98, and 100 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mitsuhashi (U.S. Patent Number 5,556,749) are maintained for reasons of record.

Applicants argue on pages 16-18 (beginning on line 4) that Mitsuhashi et al. does not disclose the steps of “forming clusters and selecting, for a cluster, a hybridization oligonucleotide where the hybridization of a hybridization probe is predicted by the presence of a hybridization oligonucleotide in the cluster”. However, this is not agreed with.

As previously indicated in the ‘*NON-FINAL OFFICE ACTION*’, mailed 26 January 2005, Mitsuhashi et al. (U.S. Patent Number 5,556,749) discloses an oligoprobe designstation allowing a user to calculate and design specific oligonucleotide probes for DNA and mRNA hybridization procedures (instant claims 17, 18, 20, and 21; cited U.S. Patent ‘Abstract’), wherein candidate probes are analyzed for their binding specificity relative to some known set of mRNA or DNA sequences (i.e. sequence database) (Column 6, lines 31-34). Mitsuhashi et al. describes the process of probe design as follows: 1) candidate probes are selected at some or all the positions along a given target (instant claim 1, step (a)); 2) a melting temperature model is selected, and an accounting is made of how many false hybridizations each candidate probe will produce and

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what the melting temperature will be (instant claim 1, steps (b) and (c)); 3) results are presented with a unique set of tools for visualization, analysis, and selection among the candidate probes (instant claim 1, steps (d) and (e); “formation of cluster and selection therein” which is discussed further below) (Column 6, lines 34-50). The design station graphically displays of the results thereby providing the user with the ability to visualize candidate probe hybridization strengths (i.e.  $T_m$ , which is “a function of probe length and GC content Column 14, lines 24-25) and the number of false hybridizations (various sources and temperatures) for all candidate oligonucleotide probes for the target sequence (instant claims 5, 7, and 9; Column 10, lines 41-59, Column 14, lines 4-16, and Figure 4). A particular probe and species within can be selected via an adjustable (i.e. flexible length) and movable window (i.e. from start to end) along the target sequence, wherein the movable window identifies a plurality oligonucleotides probe species (i.e. subset) within a plurality of regions/clusters (formation of a cluster) and allows for the selection of individual oligonucleotides inside the particularly “windowed” region/cluster based on hybridization strength (instant claim 1 steps (d) and (e); Column 14, lines 25-42, Column 15, lines 16-60, and Figure 4). To clarify Applicants’ summary/argument on page 16 (lines 22-32) in the ‘*RESPONSE*’, filed 22 April 2005, that these above cited portions of Mitsuhashi et al. teach “a graphic display of all of the candidate probes and their hybridization strengths with all sequences from the sequence database”; it is the adjustable movable window of Mitsuhashi et al. that provides for the formation of “clusters” along the target sequence and selection of a candidate oligonucleotide probe within this window. While it is acknowledged the window may form a single cluster of the entire target sequence the said widow is also indicated as being movable, wherein the user may slide the display to the left or right (Refer to Figure 4 x

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and y axis of the window). The invention runs under Microsoft Windows on IBM compatible personal computers (i.e. memory, etc.) and the results (i.e. hybridizations of probes for the target) of the invention are outputted to a graphical display (instant claims 15, 98, and 100; Column 7, lines 18-21 & 37-41, and Columns 11-12, lines 66-67 & 1-38, respectively). Thus, Mitsuhashi et al. anticipate the instantly claimed invention.

### **Claims Rejected Under 35 U.S.C. § 103**

The rejection of claims 1, 5, 7, 9, 15-18, 20, 21, and 98-101 under 35 U.S.C. § 103(a) as being unpatentable over Mitsuhashi et al. (U.S. Patent Number 5,556,749) in view of Southern (U.S. Patent Number 5,700,637) are maintained for reasons of record.

Applicants argue on page 19 in the '*RESPONSE*', filed 22 April 2005, that the combined teachings of Mitsuhashi et al. and Southern do not suggest the feature of "forming clusters and selecting a hybridization oligonucleotide wherein the hybridization of the hybridization oligonucleotide is predicted by the presence of the hybridization oligonucleotide in the cluster". However, this is found unpersuasive.

Mitsuhashi et al. is applied herein as indicated in the above 35 U.S.C. § 102(b) Rejection. As indicated above Mitsuhashi et al. does provide for the formation of clusters (i.e. movable window) and the selection of a hybridization oligonucleotide within a cluster. However, Mitsuhashi et al. fails to teach the computation of probable errors (statistics) and electronically transferring the identified oligonucleotides to an oligonucleotide array.

Southern (U.S. Patent Number 5,700,637) describes an apparatus and method for analyzing polynucleotide sequences and a method of generating oligonucleotide arrays on solid support, wherein a computer (i.e. electronically transfer data) is utilized to analyze and control

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the system (instant claims 16, 99 and 101; cited U.S. Patent 'Abstract', Columns 6-9, Example 5, and claim 2).

Southern provides motivation for the combination by disclosing numerous potential applications for the novel method of analyzing nucleotide sequences (Columns 13-17, beginning on line 31). Mitsuhashi et al. provides motivation for the combination by indicating their disclosed invention is faster, more accurate, and allows the user to perform many types of analysis on the candidate probes (Column 6, lines 51-58). Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Mitsuhashi et al. (U.S. Patent Number 5,556,749) in view of Southern et al. to utilize the computer program(s) as an efficient method to design optimal oligonucleotide probe sequences based on thermodynamic hybridizability, and transferring the resultant identified oligonucleotide probes to an oligonucleotide array manufacturing system, thereby providing a faster, more accurate, and broader application for the analysis of nucleotide sequences.

#### *OBJECTION TO CLAIMS*

Claims 2 and 3 are objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claims 102 and 122. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k).

Claims 4, 6, 8, 10-14, 19, 22-25, 27, 30-40, 102-105, 109-125, and 129-147 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



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Claims 28 and 29 are objected to because a grammatical formality, wherein "said parameters is less than about 0.5." should be corrected to recite "said parameters is are less than 0.5." Appropriate correction is requested.

*ACTION IS FINAL, NECESSITATED BY AMENDMENT*

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The Fax Center number is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: *CSM*

Date: *July 11, 2005*

*Ardin H. Marschel 7/11/05*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**